SUMMARY OF SAFETY AND EFFECTIVENESS

K972592

1. Device Name: Flex Coil for the Prestige, Privilege, and Gyrex V-EP.

1.2 Classification Name: Magnetic Resonance Diagnostic Device

1.3 Submitter: Elscint, Inc., 505 Main St., Hackensack, NJ 07601

1.4 510(k) Number:_____ SEP 15 [illegible]

2. Device Modification Description

The modification is the addition of a flexible coil to image the elbow, hand, ankle, foot, and other small extremity joints. The coil is similar in design to the predicate device, a legally marketed Flexible Coil (k944331). The only significant modification is with respect to the frequency for the 2 Tesla model because the predicate device was designed only for 0.5T, 1.0T and 1.5T systems.

3. Predicate Devices: The predicate devices are the 2T Prestige (k945791), Privilege (k954039), and Gyrex V-EP (k962618) systems with their shoulder coils, and the General Purspose Flex Coil (k944331).

4. Safety

- The MRI safety parameters, SAR, dB/dt, B_0, and acoustic noise, do not apply to passive coils.
- Electric shock hazards are avoided by enclosures designed to comply with clause 16 of the IEC-601-1 safety standard.
- Rough surfaces and sharp corners and edges which may cause injury or damage are avoided by design according to clause 23 of the IEC-601-1 standard.
- The coil enclosures and protective covers are flame rated better than CPAI-84.
- No software modifications have been made.
- All of the patient contacting materials are identical to those used in the predicate Flexible Coil (k944331).
- The current modifications do not affect the site planning, installation, or service manuals, and do not require any new safety labeling.

5. Effectiveness

The Elscint 0.5T and 2T Flex Coils have acceptable uniformity and higher SNR than the Shoulder Coil. The images produced by the Flex Coils are better than those produced using the Shoulder Coils on the same systems.

6. Substantial Equivalency Statement

Based on the above, it is Elscint's opinion that the 2T-Prestige, Privilege, and Gyrex V-EP systems with their new Flex Coils are substantially equivalent to the predicate devices in terms of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 15 1997

Beny Sherer
Safety Officer
Elscint, Inc.
505 Main Street
Hackensack, NJ 07601

Re: K972592
Flex Coil for Gyrex 0.5T and 2.0T MRI System
Dated: July 10, 1997
Received: July 11, 1997
Regulatory class: II
21 CFR 892.1000/Procode: 90 MOS

Dear Mr. Sherer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

William Yin

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K972592

Device Name: Flex Coil for Gyrex 0.5T and 2T Systems

Indications for Use:

Magnetic Resonance Imaging of small extremity joints.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seguin

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K972592

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)